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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,363	05/07/2001	Michael Franciscus W. C. Martens	294-100	2538

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/28/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/850,363	Applicant(s) MARTENS ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- Th MAILING DATE of this communication appears on th cover sheet with th correspond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Upon further consideration the restriction requirement set forth in paper number 5, Claims 15-18 are in fact dependent from claims 1-4. Therefore, claims 15-18 are regrouped with Group I for examination.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-4 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that examiner gives no basis for the idea that the apparatus of claims 1-4 can be used to determine anything other than insulin or C-peptide. This is not found persuasive because not only may the apparatus as claimed can be used to determine rubella levels it may also be used for the detection of pregnancy. Kuniyuki et al (US Patent 5,089,419) disclose the use of anti-C peptide antibodies for the detection of pregnancy by identification of the C-peptide (col 9, lines 19-43). Therefore, the apparatus as claimed may be used to practice another and materially different process such as for detection of pregnancy. This is not found persuasive because restriction requirements are set forth for reasons patentable distinction between each independent invention so as to warrant separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. The requirement is still deemed proper and is therefore made **FINAL** for reasons of record.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in European Patent Office on 3-23-01. It is noted, however, that

Art Unit: 1641

applicant has not filed a certified copy of the EPO 01201107.8 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3 the recitation "solidified" is vague. It is unclear what applicant intends.

Claim 1, line 4 "capable of" is vague and indefinite. Can the reservoir receive a sample, a wash solution, and labeled monoclonal anti-insulin or not.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1641

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coassin et al (US Patent 6,232,114) in view of Ullman et al (US Patent 6,103,537) and Goldfine et al (US Patent 5,939,269).

Coassin et al (US 6,232,114) disclose a spectroscopic measurement device comprised of multi-well (reservoir) plates which can be used for detecting a signal from a sample (col 10, lines 8-29). Coassin et al also disclose the use of a photomultiplier detector (col 21, lines 1-5). Coassin et al also disclose that these plates may be used for binding assays (col 1, 39-42) and that binding pairs may be used in the wells (reservoir) to perform these binding assays. Examples of the binding pairs include antigen/antibodies, antibody/antibody, receptor/ligand, enzyme/ligand and the like (col 3, lines 46-52). Coassin et al also disclose the use of chemiluminescent labels as a detectable marker (col 5, line 57 – col 6, line 9).

Coassin et al differ from the instant invention in failing to teach the use of monoclonal anti-insulin antibodies. Coassin et al also fail to teach the use of a wash solution in the reservoir. Coassin et al also fail to teach the use of a labeled monoclonal anti-insulin antibody.

Ullman et al (US Patent 6,103,537) disclose the use of both anti-insulin monoclonal antibodies (col 35, lines 56-67) and labeled monoclonal insulin antibodies (col 36, lines 56-67). Ullman et al also disclose that the label may be chemiluminescent (col 23, lines 60 -62). The use of these antibodies allows for photometric detection (col

Art Unit: 1641

23, line 61) and also provides the ability to measure quantitatively or to identify a wide variety of physiologically active compounds (col 1, lines 10-16).

Goldfine et al (US Patent 5,939,269) disclose the use of a wash solution received in a 96 well plate which contains anti-insulin receptor monoclonal antibodies (col 12, lines 37-48). The use of this wash solution provides for effective agents that can be used in various diagnostic and therapeutic methods for the detection and treatment of insulin resistance and related disorders (col 3, lines 16-22).

It would have been obvious to one of ordinary skill in the art to incorporate the use of both anti-insulin monoclonal antibodies and labeled monoclonal insulin antibodies as taught by Ullman et al into the device of Coassin et al because Ullman et al shows that the use of these antibodies allows for photometric detection and also provides the ability to measure quantitatively or to identify a wide variety of physiologically active compounds.

It would also have been obvious to one of ordinary skill in the art to incorporate the use of a wash solution as taught by Goldfine et al into the device of Coassin et al because Goldfine et al shows that the use of this wash solution provides for effective agents that can be used in various diagnostic and therapeutic methods for the detection and treatment of insulin resistance and related disorders.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coassin et al (US Patent 6,232,114) in view of Ullman et al (US Patent 6,103,537) and Goldfine et al (US Patent 5,939,269) as applied to claims 1, 3, and 4 above, and further in view of Milford et al (US Patent 4,517,289).

Art Unit: 1641

See above for teachings of Coassin et al, Ullman et al and Goldfine et al.

Coassin et al differ from the instant invention in failing to teach the labeled monoclonal anti-insulin antibody present in dried form.

Milford et al disclose the use of lyophilized monoclonal antibodies along with any other necessary reagents (col 8, lines 65-68). This allows for the antibody to be in stable form (col 8, line 67) and also is useful for the tissue typing of human tissues (col 3, lines 1-3).

It would have been obvious to one of ordinary skill in the art to incorporate the use of lyophilized antibodies as taught by Milford et al into the device of Coassin et al because Milford et al shows that this allows the antibody to be in stable form and also is useful for the tissue typing of human tissues.

7. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coassin et al (US Patent 6,232,114) in view of Ullman et al (US Patent 6,103,537), Goldfine et al (US Patent 5,939,269) and Milford et al (US Patent 4,517,289) as applied to claims 1-4 above, and further in view of Geary et al (US Patent 5,167,947).

See above for teachings of Coassin et al, Ullman et al, Goldfine et al, and Milford et al.

Coassin et al differ from the instant invention in failing to teach obtaining the sample by a probe arranged to be introduced in the Vena porta.

Geary et al (US Patent 5,167,947) disclose obtaining a sample by insertion of a catheter (probe) in the portal vein (col 6, lines 18-20). Obtaining this sample allowed for

Art Unit: 1641

the demonstration of the enhancement of the bioavailability of ethiofos and its active metabolite (col 5, lines 49-51).

It would have been obvious to one of ordinary skill in the art to obtain a sample as taught by Geary et al for the device of Coassin et al because Geary et al shows that obtaining this sample allows for the demonstration of the enhancement of the bioavailability of ethiofos and its active metabolite.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Nakanome et al (Immunoreactive proinsulin detected by enzyme-linked immunosorbent assay, Biomedical Research, vol. 18, 389-393, 1997) disclose a method in which two monoclonal antibodies, an anti-C-peptide antibody bound to microtiter plate and a biotin-labeled anti-insulin antibody are used.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
February 25, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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02/25/02